K061102

JUL 2 8 2006

Section 12
Appendix 12-1
Prima Anaesthesia Machine
Special 510(k): Device Modification

510(k) Summary

(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**
   Penlon Limited
   Abingdon Science Park
   Barton Lane
   Abingdon
   Oxfordshire
   POX14 3PH
   U.K.

2. **Submitter's telephone number and fax number:**
   Tel: 011 44 1235 547000
   Fax: 011 44 1235 547041

3. **Contact person:**
   Mr. Alan Green – Technical Director

4. **Date this 510(k) summary prepared:**
   March 28, 2006

5. **Trade/proprietary name of the device:**
   Prima Anaesthesia Machine

6. **Classification name and number of the device:**
   Gas Machine for Anaesthesia 21CFR 868.5160

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   1. Penlon Limited AM1000 Anaesthesia Machine – FDA 510(k) No. K844008
      Approval to market this device given by FDA on March 12, 1985
      FDA Device Classification: Class 2
      FDA Regulation Number: 21CFR 868.5160
      FDA Classification Code: BSZ
   2. Bear Medical Systems, Inc. AM1000 Anaesthesia Machine – FDA 510(k) No. K864590
      Approval to market this device given by FDA on May 4, 1987
      FDA Device Classification: Class 2
      FDA Regulation Number: 21CFR 868.5160
      FDA Classification Code: BSZ

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510(k) Summary (continued)

(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

8. **Description of the device that is the subject of this premarket notification:**
The Prima Anaesthesia Machine is a continuous flow anaesthesia gas delivery device that enables the anesthetist to deliver mixtures of oxygen, air, nitrous oxide and volatile anaesthetic agents to a patient. Although the device has no direct contact with the patient it has an important role to play in a system that delivers anaesthesia gases to a patient.

9. **Intended use and indication for use:**
The Prima Anaesthesia Machine is intended to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system, from where the anaesthesia ventilator and breathing circuit will deliver this fresh gas to the patient.

The machine is intended for use by health care providers, i.e. Physicians, Nurses and Technicians for use with patients during general anaesthesia in suitably equipped operating rooms.

The Prima Anaesthesia Machine is a prescription device and the labelling indicates this.

10. **Technological characteristics:**
The device comprises a trolley, a gas delivery system, gas control system, safety systems and facilities to mount and interface other modules of an anaesthesia delivery system, e.g. ventilators, vaporizers, absorbers plus other accessories. The design of the device conforms to all relevant national and international standards covering the safety of anesthesia systems.

Different versions of the Prima Anaesthesia Machine exist for the delivery of anaesthetics in differing locations and sizes of operating rooms e.g. in hospitals, surgery centers and doctors offices. All versions utilize the same component modules, method of construction and safety devices hence simplifying the servicing operations and minimizing the maintenance requirements of the medical center.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2006

Penlon Limited
C/O Mr. Barry Pearce
Shotwell & Carr, Incorporated
25 Barker Close Fishbourne
Chickester,
UNITED KINGDOM P0188BJ

Re: K061102
Trade/Device Name: Penlon Prima Anaesthesia Machine
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: July 6, 2006
Received: July 10, 2006

Dear Mr. Pearce:

This letter corrects our substantially equivalent letter of July 28, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

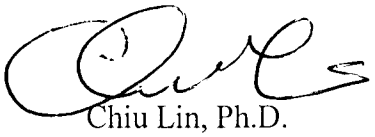
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Division Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061102

Device Name: Penlon Prima Anaesthesia Machine

Indications for Use:

The Penlon Prima Anaesthesia Machine is designed to deliver a combination of medical gases and volatile anaesthetic agents to a breathing system.

Prescription Use ___YES___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___NO___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...on Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...Number K061102